

REMARKS

Claims 1-14 and 16-28 are currently pending in the application. Claims 1-16 and 18-28 are herein canceled without prejudice. Claim 17 is in independent form.

Claim 17 has been amended to combine elements of claim 1, previous claim 17, and broader aspects of claim 19 (i.e., the catheter abuts the head of the guide tube as the fine tube is passed through the opening). All elements of claim 17 as amended have thus been searched, and no new matter has been added. Claim 17 has been amended to claim a combination of the catheter and guide tube.

Claims 1-5 and 26-28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,045,532 to Eggers, et al. Specifically, the Office Action holds that Eggers, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm and a hub (614) that represents a fitting and has a stop surface with the catheter. This rejection has been rendered moot according to the present amendment. Reconsideration of the rejection is respectfully requested.

Claims 1-12, 16, and 26-28 stand rejected under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent No. 6,517,550 to Konya, et al. Specifically, the Office Action holds that Konya, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm connected to a hub (24) at the stop surface. This rejection has been rendered moot according to the present amendment. Reconsideration of the rejection is respectfully requested.

Claims 1-14 and 16-28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,902,569 to Parmer, et al. and U.S. Patent No. 6,591,472 to Noone, et al. Specifically, the Office Action holds that Parmer, et al. discloses the catheter as claimed but fails to disclose the outer diameter being not more than 0.5 mm. The Office Action holds that Noone, et al. discloses that it is well known to use neurosurgical catheters that have small outer diameters ranging from 1

to 3 French, and therefore, it would be obvious for one skilled in the art to make the device of Parmer, et al. with a diameter as taught in Noone, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Parmer, et al. and Noone, et al. is respectfully requested.

“Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed”; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).

“The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” MPEP Section 2143.

“The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” *KSR International Co. v. Teleflex Inc.*, 83 UDPQ2d 1385, 1395 (2007) and MPEP Section 2143.

Parmer does disclose inserting a catheter (having an outer diameter of 1 mm or more) into the brain parenchyma. In particular, Parmer describes a guide device (e.g. see Figure 3, column 9, line 39 to column 10, line 32) that includes a base 210 that is attached to a hole formed in the skull, a moveable member 220 (e.g. a ball with a channel through it), an elongate guide stem 240 and a locking member 230. The moveable member is aligned using positioning stem 400 shown in Figure 3 and is then locked in place by the locking member 230. Once locked, an instrument can

be guided to the required target (column 13, lines 49-50). As shown in Figure 8 of Parmer (see also column 13, line 51 to column 14, line 20), the upper parts of the guide device can be removed over an inserted flexible instrument 229 (e.g. a catheter). This leaves the flexible instrument 229 and base 210 as shown in Figure 8a. A cap 310 can then be used to engage the base 210 and hold the flexible instrument in place. Such a cap is shown in Figure 9 (see column 14, lines 22-37). The proximal end of the flexible instrument (i.e. the bit protruding the skull) can then be tunneled subcutaneously. The catheters described in Parmer are merely flexible plastic tubes. The tubes are held in place using a clip on cap that is introduced after insertion. It can thus be seen that Parmer does not teach providing a catheter comprising a hub and a stop surface.

The Office Action argues that the terms catheter and surgical instrument are used interchangeably throughout the Parmer specification; this is incorrect because Parmer actually describes (e.g. see lines 5-10 of column 19) a catheter as being **one example** of a surgical instrument (another example mentioned is a needle). The Office Action then refers to Parmer as disclosing a hub (220) with a stop surface. The item 220 that is termed the hub by the Office Action is not a part of the catheter but is the moveable member 220 of the trajectory guide 200 (i.e. the ball which is aligned and then used to guide instruments into the brain). As stated above, Parmer only discloses catheters comprising flexible plastic tubes without any hub or stop surface.

Noone does describe catheters having an OD from 0.33 mm to 1.0 mm, but these are **intravascular** catheters. The Noone catheters are not intraparenchymal catheters of the type described in Parmer and as claimed in the present invention.

It is therefore submitted that neither Parmer or Noone, whether read alone or in combination, teach the structure of the catheter that is defined in claim 17 of the present application. Furthermore, there are no teachings in Parmer or Noone related to a guide tube structure that is inserted into brain parenchyma recited in newly amended claim 17. The only guide element used in Parmer is always located external to the skull.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

/Kenneth I. Kohn/
Kenneth I. Kohn, Reg. No. 30,955
Customer No.: 48924

Dated: July 29, 2010

CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

Date of Electronic Filing: July 29, 2010

I hereby certify that this correspondence is being electronically filed with the United States Patent & Trademark Office on the above date.

/Natalie Zemgulis/
Natalie Zemgulis